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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,736	02/20/2002	Justin R. Fallon	BURF-P02-006	2816

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EXAMINER

CHERNYSHEV, OLGA N

ART UNIT	PAPER NUMBER
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1649

MAIL DATE	DELIVERY MODE
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01/04/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/081,736	Applicant(s) FALLON ET AL.	
	Examiner Olga N. Chernyshev	Art Unit 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13, 16, 32 and 34-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13, 16, 32 and 34-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 26, 2007 has been entered.

Response to Amendment

2. Claims 13 and 39 have been amended and claims 40-44 have been added as requested in the amendment filed on October 26, 2007. Following the amendment, claims 13, 16, 32 and 34-44 are pending in the instant application.

Claims 13, 16, 32 and 34-44 are under examination in the instant office action.

3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

4. Applicant's arguments filed on October 26, 2007 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Information Disclosure Statement

5. The information disclosure statement filed on October 30, 2007 fails to comply with 37 CFR 1.98(a)(1) and (2).

The information disclosure statement filed on October 30, 2007 has been placed in the application file, but the information referred to therein has not been considered (See MPEP § 609).

Claim Objections

6. Claim 36 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claim 36 depends from claim 32, which is limited to a polypeptide of at least 90% identity to SEQ ID NO: 9, while claim 36 encompasses a polypeptide with 90% identity to the fragment of SEQ ID NO: 9. Therefore, claim 36 is of broader scope and can be infringed by a polypeptide, which does not infringe claim 32. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Applicant should note the "Infringement Test" for dependent claims in MPEP § 608.01(n). The test for a proper dependent claim is whether the dependent claim includes every limitation of the parent claim. A proper dependent claim shall not conceivably be infringed by anything, which would not also infringe the basic claim.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 13, 16, 32 and 34-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claim 13, as amended, is vague and indefinite for recitation “an abnormal dystrophin-associated protein complex (DAPC) “. Since the instant specification fails to present clear definition of what represents normal or abnormal DAPC, a skilled artisan cannot determine if a cell which meets all of the other limitations of the claim would then be included or excluded from the claimed subject matter by the presence of this limitation.

10. Claim 39 is indefinite as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the steps to assay activity of MuSK. Specifically, the claim, as currently amended, recites additional step of “assaying activity of MuSK” and it is not obvious what specific steps are intended by the claim to complete the claimed method.

11. Claims 16, 32, 34-38 and 40-44 are indefinite for being dependent from indefinite claims.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 13, 16, 32 and 34-44, as amended, are rejected under 35 U.S.C. 102(b) as being anticipated by Ruoslahti et al., US Patent No. 5,654,270 for reasons of record in previous communications of record.

At pp. 4-5 of the Response, Applicant submits that "Ruoslhti et al. do not anticipate the present invention. Ruoslahti et al. at least fail to teach, expressly or inherently, a method which involves use of a cell which has an abnormal dystrophin-associated complex (DAPC) as recited in the claimed method. Nor do Ruoslahti et al. teach a method of activating MuSK in such cell". Applicant's arguments have been careful consideration but are not persuasive for the following reasons.

As fully explained in the previous office actions of record, the instant claims 13, 16, 32 and 34-44 encompass a method for activating muscle, skeletal, receptor tyrosine kinase (MuSK) in a cell by contacting the cell with an amount of biglycan therapeutic effective to stimulate agrin-induced phosphorylation of MuSK. The patent of Ruoslahti et al. expressly describes contacting biglycan of 100% structural identity with the instant polypeptide of SEQ ID NO: 9 with the cells (treating wounded muscular tissue), thus fully meeting all the limitations of the claims. Since the instant specification fails to specifically point out what represents an abnormal DAPC, see reasons of record in section 9 of the instant office action, the disrupted muscular tissue of the wound, by broadest reasonable interpretation fully encompasses cells with abnormal DAPC, absence evidence to the contrary.

MPEP 2112 clearly states

"[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition

patentably new to the discoverer.” *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also *Ex parte Novitski*, 26 USPQ2d 1389 (Bd. Pat. App. & Inter. 1993) “The discovery of an inherent property of a prior art process can not serve as a basis for patenting that process”.

In the instant case, since the claims are not particularly limited to a specific effective concentration of biglycan, or recitation of novel steps for achieving activation of MuSK, the same process of contacting wounded muscular cells with the product of identical structure, biglycan of SEQ ID NO: 9, is fully anticipated by the document of Ruoslahti et al.

Applicant is advised that because biglycan therapeutic has been shown to have a biphasic effect on cell activation (Example 10, p. 83), including the concentration range, which enables practicing the instant method, would distinguish the instant claims and the prior art of record.

Double Patenting

14. Claim 44 is rejected on the ground of nonstatutory double patenting over claims 1-14 of U. S. Patent No. 6,864,236 since the claim, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: claim 1 of the instant application is generic to and fully encompasses the claimed subject matter of claims 1-14 of '236 Patent.

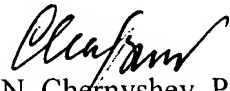
Conclusion

15. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey J. Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Olga N. Chernyshev, Ph.D.
Primary Examiner
Art Unit 1649

December 28, 2007